

REMARKS

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are pending. Claims 1, 38, and 39 are amended herein. After entry of this Amendment, Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are under consideration. Support for these amendments can be found in the language of the original claims, throughout the specification, and at least at paragraphs [0027], [0090], [0134], [0146], and [0256] of U.S. Publication No. 20010041188. It is believed that no new matter is added. In light of the following remarks, Applicants respectfully request reconsideration of this application, entry of this Amendment, and allowance of the claims to issue.

Applicants appreciate the detailed Office Action and the explicit reasoning provided by the Examiner. Applicants respectfully submit that the current claims recite a device with structural difference from the prior art and that the device is patentably distinct from the prior art.

35 U.S.C. § 103(a)

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Murdock, U.S. Publication No. 2002/0042587, herein “Murdock”, in view of Marans, U.S. Patent No. 3,511,764, herein “Marans” and Ladin, U.S. Patent No. 5,792,090, herein “Ladin”. Applicants traverse this rejection as applied to the currently pending claims.

The Office Action stated that “Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036).” See Office Action page 5. Additionally, the Office Action stated “Murdock does not explicitly teach polyacrylamide polymer as claimed in claims 1, 38 and 39. Although Murdock teaches closed cell foam containing gas that can be produced chemically, however, the reference does not explicitly teach the specific chemical reaction that produces the gas in the foam as claimed in claims 1, 38 and 39.” See Office Action, page 6. Further stated was “Therefore, at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically in the foam as taught by Murdock.”

The Office Action stated that “Marans teaches cross-linked polyacrylamide foam foamed by decomposition product of another polymer during manufacture of the polymer to provide uniform closed cell foam matrix that swells and absorbs water but does not dissolve. Foaming of polyacrylamide was performed during the manufacture of the polyacrylamide crosslinked polymer (See the entire document, and especially col.1, lines 12-16, 20-26; col.2, lines 54-59; col.4, lines 6-8). See Office Action page 5.

The Office Action stated that “Ladin teaches wound dressings that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26).” See Office Action Page 5. The Office Action further stated “forming oxygen in a foam matrix by chemical reaction between peroxide and catalyst was known at the time of the invention as taught by Ladin.” See Office Action page 7.

The Office Action stated that that

it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam wound dressing containing oxygen that can be produced chemically as disclosed by Murdock, and replace the closed cell cross-linked polymer foam with crosslinked polyacrylamide closed cell foam that taught by Marans.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the crosslinked polyacrylamide closed cell foam containing oxygen in the bubbles as disclosed by the combination of Murdock and Marans, and further produce the oxygen during the formation of the foam by the reaction of hydrogen peroxide and catalyst as disclosed by Ladin. See Office Action page 7.

Marans teaches polymeric foam reservoirs for an electrotransport delivery device. See the Title, specification and claims of Murdock. Murdock does not teach wound treatment. The polymeric reservoir of Murdock incorporates gases into a polymeric matrix such that the resulting reservoir has a relatively high surface area and provides a reservoir that enables smaller quantities of drug to be loaded into the system. Murdock, paragraphs [0009] and [0016]. The gas bubbles act as an inert filler, increasing the surface area of the matrix without introducing the drawbacks of comment ‘inert’ fillers, such as glass beads, titanium dioxide,

quartz powder, polymer powders, etc., to which therapeutically active agents may bind.” Murdock, paragraph [0034]. No gas is released from the bubbles in the Murdock reservoir. The bubbles function like glass beads, titanium dioxide, quartz powder, polymer powders- they merely take up space and have no other function. If the gases were to be released, purpose of the Murdock polymeric reservoir would be destroyed.

The Office Action responds to this argument by stating that “the reference [Murdock] teaches more than one method of foaming...” The method of foaming does not change the teaching of Murdock that the bubbles formed are inert. The Office Action stated that “the foam is capable of delivering active agents.” There is no teaching in Murdock that the bubbles have any function other than space-filling, and there is no teaching that the bubbles deliver active agents. See Office Action, page 9.

The Office Action stated that “Delivery of oxygen is taught by Ladin. The combination of the references teaches closed cell foam of crosslinked polyacrylamide containing oxygen in the closed cells, which is the product currently claimed. It is expected that when the product taught by the combination of the prior art is exposed to the same environment, such as wound, culture media, package, etc., the product will behave the same way and react with the environment and release active agents and/or oxygen since materials and their properties are inseparable. The burden is on applicants to show that the closed cell crosslinked polyacrylamide foam containing oxygen in the cells that is taught by the prior art will not deliver oxygen under the same environmental circumstances.” Office Action, Page 9.

Applicants have met this burden and have shown that closed cell crosslinked polyacrylamide foam containing oxygen in the cells, made by the method of Murdock and containing oxygen as taught by Ladin, “does not deliver oxygen under the same environmental circumstances” when compared the Applicants’ currently claimed invention. Applicants have submitted Gibbins Declaration, February 14, 2007, with data that shows that the Murdock device, does not release oxygen, see Figures 1 and 2, whereas Applicants’ currently claimed device releases an increasing amount of oxygen “under the same environmental circumstances”. The total mount of deliverable oxygen in the Murdock device after 24 hours was < 0.1 ppm oxygen, whereas “under the same environmental circumstances”, Applicants’ currently claimed device released approximately 2.8 ppm oxygen. Applicants have enclosed a copy of the Gibbins Declaration with this Response.

Applicants specification teaches that oxygen is released from the currently claimed device, see at least at Figures 1 and 2, of U.S. Patent Publication No. 20010041188. The oxygen that is released by the currently claimed device is capable of keeping living organisms alive, see Figure 3 of U.S. Patent Publication No. 20010041188. The Office Action responded to Applicants' argument that the closed cells of Murdock and Marans do not change or interact with the environment by stating "A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." The prior art structure is not capable of performing the intended use, as evidenced by the teachings of the prior art and the experiments conducted by Applicants. The prior art does not "meet[s] the claim". Applicants currently pending claims recite a structural difference between the claimed invention and the prior art- the currently claimed invention delivers oxygen from elastic closed cells that are permeable to gas. The currently pending invention is patentably distinct from the prior art. Applicants request the Examiner to withdraw the rejection.

Marans teaches a cross-linked polyacrylamide foamed by the decomposition of another polymer, i.e., polyoxymethylene. The foamed product formed is "useful as a packing material, insulation, water absorption material," and there is no teaching or suggestion that the gaseous polyoxymethylene decomposition product is released from the matrix. See Col. 4, lines 5-7. Moreover, Marans never mentions or suggests generating oxygen in cross-linked polyacrylamide to be delivered to a wound for therapeutic purposes. The gas entrapped in the polyacrylamide matrix of Marans is not therapeutic oxygen; instead the gas comprises breakdown products of polyoxymethylene, a substance that cannot safely be used for treating wounds.

The Office Action response to the argument that Marans is unsuitable for combination with Murdock or Ladin, by stating, "the '764 patent [Marans] is relied upon for the sole teaching that polyacrylamide polymers were known at the time of the invention and to showing of polyacrylamide during manufacture is known at the time of the invention. Foaming using the claimed catalyst and reactant is taught by Ladin."

Foaming is not taught in Ladin. Ladin teaches "Abutting the outer surface of the oxygen permeable membrane, that is, the surface which will be located exterior to the wound with respect to the oxygen permeable membrane, is a reservoir containing a renewable, nonsustaining

chemical oxygen source...the physical device may contain an empty volume adapted to receive an oxygen generating liquid composition; may be a sponge-like or open-celled foam of natural, synthetic, or mixed natural/synthetic origin; or may comprise a solid.." See Col. 5, lines 51-61. There is no teaching of foaming any material.

Applicants have previously submitted that polyacrylamide, the teaching of Marans, cannot be polymerized in the presence of oxygen, the production of which is taught by Ladin. In response to this argument, the Office Action stated that "as indicated repeatedly supra, US '764 [Marans] is relied upon for teaching the type of polymer used to form the crosslinked foam, which is polyacrylamide, and to show that at the time of the invention it was known to use crosslinked polyacrylamide polymer to form closed cell foam wherein foaming is done during the process of manufacture of the foam, as taught by US '764 [Marans]." See Office Action, page 13.

Additionally, the Office Action stated "Further, the combination of US '587 [Murdock] and US '764 [Marans] teaches product comprising oxygen within closed cell foam of cross-linked polyacrylamide matrix, and US '764 [Marans] further teaches to form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer. US '090 [Ladin] teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen. Therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells containing oxygen produced by the chemical reaction between catalyst and reactant as instantly claimed. The invention as a whole is taught by the combination of the references." See Office Action page 16. and on page 18, "Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix. Additionally, regarding the order of steps, it is argued that US '587 teaches product comprising oxygen within the cross-linked matrix, and US '090 teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen, therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells containing oxygen. The invention as a whole is taught by the combination of the references."

Applicants currently claimed invention is a product that delivers oxygen from elastic closed cells that are permeable to oxygen. Applicants have disclosed an invention that has superior and unexpected results, a device that delivers oxygen, when compared to the prior art

combination that does not deliver oxygen or any gas. A recitation that oxygen production is taught (Ladin) and that polyacrylamide can be foamed [Marans] cannot ignore the physical reality that polyacrylamide does not substantially polymerize in the presence of oxygen. Marans does not teach a foaming process for polyacrylamide during manufacture that uses oxygen to create a foamed article. All logical reasoning cannot overcome the fact that these references cannot be combined to make a device of polyacrylamide that has elastic closed cells that are permeable to gas that contain oxygen and that the oxygen is delivered from the closed cells. Applicants are not claiming a combination of elements of the prior art, and the device of Applicants' currently pending claims is much more than the predictable use of prior art elements according to their established functions. Applicants currently claimed device is neither taught nor suggested by the combination of the cited references or by the references individually. Applicants respectfully request the Examiner to withdraw the rejection and allow the pending claims.

CONCLUSION

The foregoing is a complete response to the Office Action dated February 25, 2010. Applicants respectfully submit that at least Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicants respectfully request the Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

A credit card payment submitted via EFS Web in the amount of \$3,160.00 (representing \$2,350.00 for the fee for a large entity under 37 C.F.R. § 1.17(a)(5) and \$810.00 for the fee for a large entity under 37 C.F.R. § 1.114)), a Request for Continued Examination, and a Petition for a five-month extension of time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

Respectfully submitted,

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